6/5/00 gm

AUG 9 2000

K001764

Summary of Safety and Effectiveness

510(k) Premarket Notification for the HOTLINE® 2 Fluid Warmer

US FDA, Division of General, Restorative and Neurological Devices (DGRND) General Surgery Devices

The following information is provided in accordance with 21 CFR 807.92(a):

1. Sponsor name and address:

   SIMS® LEVEL 1®, Inc.
   160 Weymouth Street,
   Rockland, MA. 02370

2. Sponsor telephone number: 781-878-8011, Ext. 730

3. Contact Person: Gabriel J. Muraca, Jr. – Manager Regulatory Affairs

4. Date summary was prepared: June 5, 2000

5. Device Name: **HOTLINE®2 Fluid Warmer**

6. Common Name: FDA has identified this device as a nonelectromagnetic warming device for blood products and intravenous solutions prior to patient administration under gravity flow conditions. It is a Class II medical device, as described in 21 CFR 864.9205.

7. The legally marketed predicate device, which is currently in US commercial distribution, is the **SIMS® LEVEL 1® HOTLINE® Fluid Warmer**.

Gabriel J. Muraca, Jr.
Manager RA 6/5/00

8. Description of device:

The **HOTLINE 2** is designed for use with the **HOTLINE 2** Warming Set to warm blood and intravenous solutions to deliver them to the patient access site at normothermic temperatures under gravity flow conditions. It consists of a warming device (hardware, HL-290) and the **HOTLINE 2** Warming set (disposable, L-270), that is designed for use only with this warming device. The **HOTLINE 2** Fluid Warmer is indicated for the warming of blood products and intravenous solutions prior to patient administration under gravity flow conditions. It is intended for use by appropriately trained healthcare professionals in clinical environments.

9. Indications for use:

The **HOTLINE 2** Fluid Warmer is indicated for the warming of blood products and intravenous solutions prior to patient administration under gravity flow conditions. It is intended for use by appropriately trained healthcare professionals in clinical environments.

10. Technological characteristics:

There are no significant changes in technological characteristics or intended use that impact the safety or effectiveness of the device. However, as described in this submission, **Level 1** has made design modifications to improve the performance capabilities of the **HOTLINE 2**. The data enclosed provide scientific evidence to support our substantial equivalence determination and demonstrate the **HOTLINE 2** is safe and effective for its intended use.

The **HOTLINE 2** Fluid Warmer consists of a warming device (hardware, HL-290) and the **HOTLINE 2** Warming set (disposable, L-270), that is designed for use only with this warming device. The disposable, L-270, incorporates a heated sterile non-pyrogenic fluid path to the patient. Warming is achieved by jacketing this separate sterile pathway to the patient with a layer of precisely controlled circulating warm water. The **HOTLINE 2** has a water supply heated to 41.5°C +/- 0.5°C. A "watch-dog" circuit will visually and audibly alarm, stopping the circulating water pump, if the temperature exceeds 1.2°C. The **HOTLINE** and **HOTLINE 2** are manufactured and certified in compliance with applicable International and US standards.

Gabriel J. Muraca Jr.

Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
SIMS® LEVEL 1®, Inc.

June 5, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2000

Mr. Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
Sims Level 1, Incorporated
160 Weymouth Street
Rockland, Massachusetts 02370

Re: K001764
Trade Name: Hotline 2 Fluid Warmer
Regulatory Class: II
Product Code: LGZ
Dated: June 5, 2000
Received: June 12, 2000

Dear Mr. Muraca:

This letter corrects our substantially equivalent letter of August 9, 2000 regarding the Company Name, Product Code and Regulatory Class.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center of Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K001764

Device Name: **HOTLINE® 2 Fluid Warmer**

Indications for Use:

The **HOTLINE 2** Fluid Warmer is indicated for the warming of blood products and intravenous solutions prior to patient administration under gravity flow conditions. It is intended for use by appropriately trained healthcare professionals in clinical environments.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Patricia Cusenza

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001764